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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,602	09/05/2000	Anders Carlsson	13454NP	4856

7590 10/06/2003

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EXAMINER	
GOLLAMUDI, SHARMILA S	

ART UNIT	PAPER NUMBER
1616	22

DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/632,602	HOWARD ET AL.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of Request for Continued Examination, Extension of Time, and Amendment F received on July 14, 2003 is acknowledged. Claims 1-13 are pending in this application.

Response to Arguments

Applicant argues that the instant invention has an increased local effect than normally expected. It is argued that agents have a time period of effect and the "prolonged" time frame is longer than the active. Lastly, unexpectedness is argued.

Applicant's arguments have been fully considered but they are not persuasive. US patent 6,068,860 discloses that the composition allows for an increased amount of a drug penetration at a given site but also the accumulation of an increased amount of drug at the site. Although the applicant argues that this is a different goal, the examiner points out that the duration of a drug's effectiveness is inherently increased if the drug is allowed to accumulate at a site. This accumulation allows for a continued dose at the site, which is in essence is prolonging the effective action of the drug since there is more of the drug to treat the area.

Secondly in regards to the time period, applicant's definition is vague since there are numerous active agents with various windows of activity. Therefore, the prior art still reads on instant invention.

Lastly in regards to the unexpected results in the specification, the results are not a direct comparison with the prior art and are not commensurate in scope.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-7, 9-11, and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Carlsson et al (6,068,860).

Carlsson et al disclose a pharmaceutical formulation containing a glucocorticoid, foscarnet, and galactolipids (example 5). The composition provides an anti-inflammatory agent to the skin. See column 4, lines 15-17. The galactolipids are from oats (example 5). The galactolipid material further contains 70-80% digalactosyldiaacylglycerol and 20-30% of other polar lipids. See column 5. The reference teaches the actives dissolved or encapsulated in a liposome containing galactolipids, which penetrates the skin rapidly provides an improved accumulation of foscarnet in the living epidermis, it can sustain a high concentration of the active, and is chemically and physically stable (col. 4, lines 10-25 and col. 10, line 35 to col. 11, lines 60). Further, glycerol is taught. See examples.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9 and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carlsson et al (5,688,528) in view of Brodin et al (5,912,271).

Carlsson et al teach an oil-in-water emulsion containing galactolipid material as an emulsifer in the amount of 0.1-10% and active agents. The composition may be formulated for topical administration. See column 4, line 35. The galactolipid material consists of about 70-80% digalactosyldiacylgylcerol and 20-30% of other polar lipids. See column 2, lines 42-45. The galactolipid material is prepared from oat kernels. See examples. The composition may contain other conventional excipients such as thickening agents, preservatives, antioxidants, etc. See column 3, lines 48-52 and examples. The preservatives, thickeners, and oils are taught in the instant amounts. See examples. The inclusion of dermatological agents and linoleic acids are taught in column 3, lines 28-67 Glycerol is taught in example 18 with an anaesthetic drug. Lastly, Carlsson teach the galactolipid material affords stability to the formulations.

Carlsson et al do not specify the function of the galactolipid.

Brodin et al teach a topical pharmaceutical preparation for anaesthetic agents. The composition contains the active agent in the amount of 1-40%, a polar lipid (galactolipid) in the amount of 1-10%, triglycerol in the amount of 50-85%, and water. See column 2, lines 11-25. Brodin teaches that the polar lipids, sphingolipids or galactolipids have a dual function of reducing the onset time and extent the duration of the active agent and acting as a dispersing agent and stabilizer in the formulation.

Brodin results indicate the polar lipids function of prolonging the effect of the active agent. See column 5.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Carlsson et al and Brodin et al and expect the galactolipid formulation of Carlsson's to have a prolonged effect. One would have be motivated to do so since Brodin teaches the functional property of galactolipid to prolong the effectiveness of the active agent. Therefore, although Carlsson does not explicitly disclose this functional property of the galactolipid in the formulation, one would expect this property in Carlsson's formulation since "prolonged effectiveness" is known in the art at the time the invention was made.

Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carlsson et al (5,688,528) in view of Brodin et al (5,912,271), in further view of Cooper et al (4,552,872).

AS set forth above, Carlsson et al teach an oil-in-water emulsion containing galactolipid material as an emulsifer in the amount of 0.1-10% and active agents such as dermatological agents. Brodin et al teach the functional property of galactolipids.

The references do not teach the inclusion of a corticosteroid.

Cooper et al teach a topical composition containing corticosteroid for inflammatory conditions such as atopic dermatitis. See abstract and column 12, lines 13.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the references and utilize

corticosteroid for the treatment of dermatitis. One would be motivated to do so since Cooper teaches the use of corticosteroids for the treatment of inflammatory conditions such as dermatitis.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SSG

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600